REMARKS/ARGUMENTS

The Office Action mailed June 23, 2005 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims presented for examination are: claims 1-31.

Specification

The Specification has been amended to add a "CROSS-REFERENCE TO RELATED APPLICATIONS" paragraph identifying a continuation of this application. The continuation was filed April 3, 2002 and added additional inventors Mark S. Humayun and James D. Weiland and added additional claims.

Restriction Requirement

In numbered paragraphs 1-3 of the Office Action mailed June 23, 2005, the Examiner confirmed restriction of prosecution of the above-captioned application to one of the inventions as grouped below. The Examiner supports the requirement for restriction under 35 U.S.C. 121.

Groups

I. Claims 1-31, drawn to artificial vision system, classified in class 607, subclass 116.

II. Claims 32-39, drawn to a method of processing, classified in class 29, subclass 825.

III. Claims 41-56, drawn to a system for fabricating, classified in class 216, subclass 24.

Response to Restriction Requirement

Applicants have elected, without traverse, the claims of group I, claims 1-31, drawn to artificial vision system, classified in class 607, subclass 116.

Drawings

In numbered paragraphs 4 of the Office Action mailed June 23, 2005, the drawings were objected to under 37 CFR 1.83(a) as not showing the barbs, hooks and tacks recited in claims 13, 23, and 30. Applicants have cancelled claims 13, 23, and 30. With the cancellation of claims 13, 23, and 30 Applicants believe they overcome the objection to the drawings and have provided a full and complete response to the 37 CFR 1.83(a) rejection in the Office Action mailed June 23, 2005.

35 USC 101 Rejection

In numbered paragraphs 5 of the Office Action mailed June 23, 2005, claims 19-21 and 25-31 were rejected under 35 U.S.C. 101 because the claims positively recite a part of the human body.

Applicants have amended claims 19-21 and 25-28 and have cancelled claims 29-31. Applicants believe amended claims 19-21 and 25-28 do not positively recite a part of the human body because the parent claims use the terminology "for contacting" suggested by the Examiner and because the terminology "the" is used relating back to the preamble. Applicants believe they have overcome the rejection under 35 U.S.C. 101 and that a full and complete response to the 35 U.S.C. 101 rejection in the Office Action mailed June 23, 2005 has been provided.

35 USC 112 Rejection

In numbered paragraphs 6 of the Office Action mailed June 23, 2005, claim 7 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of the term "said conductive leads." Applicants have amended claim 7 to depend from claim 2 and claim 2 introduces the term "conductive leads" with the phrase, "The electrode array of claim 1, including conductive leads." Accordingly, the term "said conductive leads" in claim 7 now has an antecedent basis in claim 2. Applicants believe they overcome the rejection under 35 U.S.C. 112 and that a

full and complete response to the 35 U.S.C. 112 rejection in the Office Action mailed June 23, 2005 has been provided.

35 USC 102 Rejection

In numbered paragraphs 9 and 10 of the Office Action mailed June 23, 2005, claims 1-3 and 6 were rejected under 35 U.S.C. 102(b) as being anticipated by the Edell reference (U.S. Patent No. 5,476,494). Applicants have amended independent claim 1 and dependent claims 2 and 6 presented for examination. Claim 3 has been cancelled. Since claims 1, 2, and 6 are now presented in amended form the 35 USC §102(b) rejection in the Office Action mailed June 23, 2005 no longer applies.

The Edell Reference

The Edell reference shows a cantilever 40 made of silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials which exhibit some flexibility. This is specifically stated in the Edell reference which describes a cantilever 40 made of "silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials which exhibit some flexibility" (Col. 4, lines 45-47 of the Edell reference).

In the Edell reference an encapsulation layer 24 of silicone material encapsulates the silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials cantilever 40. This is clear from the Edell reference which specifically states, "encapsulation layer 24 surrounds the cantilever structure 40" and the encapsulation layer 24 is "preferably of silicone material" (Col. 5, lines 62-64 of the Edell reference).

The cantilever 40 made of silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials which is encapsulated by the encapsulation layer 24 of silicone material is illustrated in FIG. 3 of the Edell reference. A copy of FIG. 3 of the Edell reference is provided below with insert added that identify the

cantilever 40 made of "silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials which exhibit some flexibility" and the "encapsulation layer 24 preferably of silicone material."

The Edell reference does not show Applicants' claimed "conformable substrate composed entirely of a flexible and stretchable polymer" or "wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) and said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes."

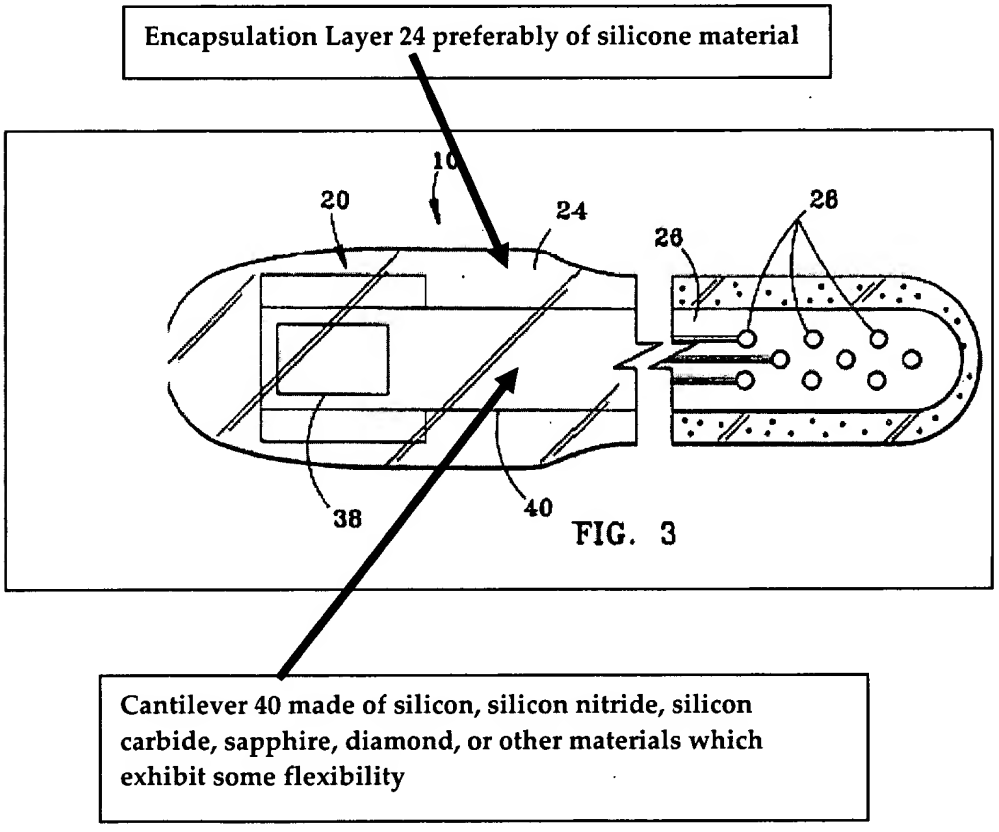


FIG. 3

Applicant points out that the following elements of Applicants' amended claims 1, 2, and 6 are not found in the Edell reference:

> "a conformable substrate composed entirely of a flexible and stretchable polymer that has the ability to conform to various shapes of the tissue" (Independent claim 1 and dependent claims 2 and 6), or

"wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) and said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes" (Independent claim 1 and dependent claims 2 and 6).

The invention claimed in amended claims 1, 2, and 6 is not anticipated by the Edell reference. The standard for a 35 USC §102 rejection is stated in RCA Corp. v. Applied Digital Systems, Inc, 221PQ 385, 388 (d. Cir. 1984) "Anticipation is established only when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention." Since the elements of Applicants' amended claims 1, 2, and 6 described above are not found in the Edell reference, the Edell reference would not support a 35 USC §102 rejection.

35 USC 103 Rejection – Edell and Pinchuk References

In numbered paragraphs 11-14 of the Office Action mailed June 23, 2005, claims 4, 5, 14, 15, 17-21, 24-28, and 31 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Edell reference in view of the Pinchuk reference (U.S. 5,741,331).

Applicants have cancelled claims 4, 5, 17, 24, and 31. Applicants have amended independent claims 1, 18, and 25; therefore claims 14, 15, 18-21, and 25-28 are now presented in amended form. Since claims 14, 15, 18-21, and 25-28 now appear in amended form the 35 USC §103(a) rejection in the Office Action mailed June 23, 2005 no longer applies.

Applicants believe that amended claims 14, 15, 18-21, and 25-28 are patentable and that the Ebell and Pinchuk references would not support a 35 USC §103(a) rejection. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a

background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Ebell reference and Applicants' invention defined by amended claims 14, 15, 18-21, and 25-28 includes the fact that the following elements of amended claims 14, 15, 18-21, and 25-28 are not found in the primary Ebell reference:

> "a conformable substrate composed entirely of a flexible and stretchable polymer that has the ability to conform to various shapes of the tissue" (Independent claim 1 and dependent claims 14 and 15), or
>
> "wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) and said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes" (Independent claim 1 and dependent claims 14 and 15), or
>
> "an electrode array including a conformable polymer substrate, said polymer substrate being a flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) and having the ability to conform to the shape of the retina" (Independent claim 18 and dependent claims 19-21), or
>
> "wherein said conformable substrate composed entirely of a flexible and stretchable polymer composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes" (Independent claim 18 and dependent claims 19-21), or
>
> "an implant connected to the eye and the retina consisting of a flexible polymer substrate, said flexible polymer substrate consisting of poly(dimethylsiloxane) and being flexible and stretchable and having the ability to conform to the shape of the retina," (Independent claim 25 and dependent claims 26-28), or
>
> "micro-stimulator electrodes embedded in said flexible polymer substrate consisting of poly(dimethylsiloxane)" (Independent claim 25 and dependent claims 26-28).

There is no legitimate combination of the secondary Pinchuk reference with the primary the Ebell reference to support a 35 USC §103(a) rejection. The secondary Pinchuk reference is strictly directed to "vascular grafts, endoluminal grafts, intraocular lenses, finger joints, indwelling catheters, pacemaker lead insulators, breast implants, heart valves, knee and hip joints, vertebral disks, meniscuses, tooth liners, plastic surgery implants, tissue expanders, drug release membranes, subcutaneous ports, injection septums, etc." (Col. 1, lines 34-40 of the Pinchuk reference) The Pinchuk reference is not directed to an electronic device and does not take the problems of an electronic device or the background of electronic devices into consideration.

Applicants point out that "Silicon" is well known as a material used as the substrate for an electronic device; however, "poly(dimethylsiloxane) or silicone" has not been known as a material used for a substrate support for an electronic device. "Silicone" is best known as the material used in breast implants. The article, "What is Silicone?" in www.silicone-review.gov.uk/silicone, provides the following definitions:

> "Silicon is the second most abundant element in the earth's crust, comprising around 28% of it. It is not found in its elemental form but occurs mainly as oxides and silicates. In contrast to carbon, silicon-silicon bonds are uncommon. Natural silicon-carbon bonds are extremely rare but they can be created synthetically."

> "Silicones are synthetic polymers and are not therefore found naturally. They have a linear, repeating silicon-oxygen backbone akin to silica. However, organic groups attached directly to the silicon atoms by carbon-silicon bonds prevent formation of the three-dimensional network found in silica. These types of compound are also known as polyorganosiloxanes. Certain organic groups can be used to link two or more of these silicon-oxygen backbones and the nature and extent of this crosslinking enables a wide variety of products to be manufactured. The most important materials used in medical implants are fluids, gels and

rubbers (elastomers) whose physical and chemical properties include, amongst others, a high degree of chemical inertness, thermal stability and resistance to oxidation."

"Silicone gels have lightly cross-linked polysiloxane networks, swollen with PDMS fluid to produce a cohesive mass. The PDMS fluid is not chemically bound to the crosslinked network but is retained only by physical means, as water is in a sponge, and there is a tendency for the fluid to "bleed." The degree of cross-linking and amount of fluid affects the physical properties of the gel and the rate at which fluid "bleeds" from it. Once suitably cross-linked, silicone gels retain their form without external containment."

The use of poly(dimethylsiloxane) as the support for a "microelectrode array" electronic device has been recognized as a scientific breakthrough. The article, "Livermore Scientists Join DOE Consortium in Partnering with Private Company to Develop Artificial Retina," in www.nanoinvestornews.com/modules.php?name=News&file=friend&op=FriendSend&sid=3574 - 26k, on October 20, 2004, describes the use of silicone (poly(dimethylsiloxane) in a microelectrode array as "PIONNEERING" and states: "The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Energy Secretary Spencer Abraham said. "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see. .... Lawrence Livermore partnered with four other national laboratories, three universities and Second Sight on the project. .... LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina." A copy of the article is attached.

Applicants' claimed invention is unobvious and there could be no legitimate combination of the secondary Pinchuk reference with the primary Ebell reference to support a 35 USC §103(a) rejection. In the Ebell reference the silicone encapsulation layer 24 is strictly used for encapsulating the support cantilever 40 of silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials which exhibit some flexibility. Applicants' claimed invention utilizes a "conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes."

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The proposed combination of the Ebell reference and the Pinchuk reference does not support a rejection of Applicants' amended claims 14, 15, 18-21, and 25-28 under 35 USC 103, and the rejection should be withdrawn.

35 USC 103 Rejection – Claims 7-12 over Edell Reference

In numbered paragraphs 15 of the Office Action mailed June 23, 2005, claims 7-12 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Edell reference.

Applicants have amended independent claim 1; therefore dependent claims 7-12 are now presented in amended form. Since claims 7-12 now appear in amended form the 35 USC §103(a) rejection in the Office Action mailed June 23, 2005 no longer applies.

Applicants believe that amended claims 7-12 are patentable and that the Ebell reference would not support a 35 USC §103(a) rejection. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the Ebell reference and Applicants' invention defined by amended claims 7-12 includes the fact that the following elements of amended claims 7-12 are not found in the Ebell reference:

> "a conformable substrate composed entirely of a flexible and stretchable polymer that has the ability to conform to various shapes of the tissue" (Independent claim 1 and dependent claims 7-12), or
>
> "wherein said conformable substrate is composed entirely of poly(dimethylsiloxane) and said conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes" (Independent claim 1 and dependent claims 7-12).

The Ebell reference does not show or suggest the elements identified above and the Edell reference would not support a 35 USC §103 rejection.

The use of poly(dimethylsiloxane) for an entire electronic device has been recognized as a scientific breakthrough and Applicants' claimed "conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes" is unobvious. The article, "Livermore Scientists Join DOE Consortium in Partnering with Private Company to Develop Artificial Retina," in www.nanoinvestornews.com/modules.php?name=News&file=friend&op=FriendSend&sid=3574 - 26k, on October 20, 2004, describes the use of silicone (poly(dimethylsiloxane) in a microelectrode array as

"PIONNEERING" and states: "The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Energy Secretary Spencer Abraham said. "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see. .... Lawrence Livermore partnered with four other national laboratories, three universities and Second Sight on the project. .... LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina." As stated previously, a copy of the article is attached.

Applicants' claimed invention is unobvious and there could be no legitimate combination of the secondary Pinchuk reference with the primary Ebell reference to support a 35 USC §103(a) rejection. In the Ebell reference the silicone encapsulation layer 24 is strictly used for encapsulating the support cantilever 40 of silicon, silicon nitride, silicon carbide, sapphire, diamond, or other materials which exhibit some flexibility. Applicants' claimed invention utilizes a "conformable substrate composed entirely of poly(dimethylsiloxane) provides the support for said micro-stimulator electrodes."

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The proposed combination of the Ebell reference and the Pinchuk reference does not support a rejection of Applicants' amended claims 7-12 under 35 USC 103, and the rejection should be withdrawn.

35 USC 103 Rejection – Claim 13 over Edell and Kuzma References

In numbered paragraphs 16 and 17 of the Office Action mailed June 23, 2005, claim 13 was rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Edell reference in view of the Kuzma reference (U.S. 6,038,484). Applicants have cancelled claim 13.

35 USC 103 Rejection – Claim 16 over Edell and Kuzma References

In numbered paragraphs 18 and 19 of the Office Action mailed June 23, 2005, claim 16 was rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Edell reference in view of the Kuzma reference (U.S. 6,038,484). Applicants have cancelled claim 16.

35 USC 103 Rejection – Claims 22 and 29 over Edell, Pinchuk, and Humayun References

In numbered paragraphs 20, 21, and 22 of the Office Action mailed June 23, 2005, claims 22 and 29 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Edell, Pinchuk, and Humayun References. Applicants have cancelled claims 22 and 29.

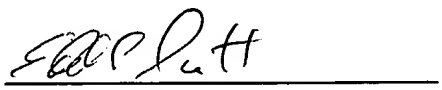
35 USC 103 Rejection – Claims 23 and 30 over Edell, Pinchuk, and Humayun References

In numbered paragraph 23 of the Office Action mailed June 23, 2005, claims 23 and 30 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the Edell, Pinchuk, and Humayun References. Applicants have cancelled claims 23 and 30.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated June 23, 2005 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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Livermore, California
Dated: September 13, 2005

Silicone Gel Breast Implants

The Report of the Independent Review Group

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What is silicone?

1. The difference between silicon, silica and silicone

Silicon is the second most abundant element in the earth's crust, comprising around 28% of it. It is not found in its elemental form but occurs mainly as oxides and silicates. In contrast to carbon, silicon-silicon bonds are uncommon. Natural silicon-carbon bonds are extremely rare but they can be created synthetically.

Silica is a three dimensional network of silicon dioxide, most commonly encountered as sand. Silica exists in crystalline and amorphous forms. Silica is chemically resistant at ordinary temperatures but can undergo a variety of transformations at high temperatures (greater than 500°C) and pressures. The industrial production of amorphous silica requires temperatures of 500°C and much higher temperatures are required to produce crystalline silica.

The prolonged inhalation of crystalline silica dust is associated with silicosis. Amorphous silica is much less pathogenic than crystalline forms. Conversion of amorphous to crystalline silica cannot occur at body temperature. High purity amorphous silica is used as a reinforcing agent to increase the tear resistance of silicone rubbers used in medical devices and implants.

Silicones are synthetic polymers and are not therefore found naturally. They have a linear, repeating silicon-oxygen backbone akin to silica. However, organic groups attached directly to the silicon atoms by carbon-silicon bonds prevent formation of the three-dimensional network found in silica. These types of compound are also known as polyorganosiloxanes. Certain organic groups can be used to link two or more of these silicon-oxygen backbones and the nature and extent of this crosslinking enables a wide variety of products to be manufactured. The most important materials used in medical implants are fluids, gels and rubbers (elastomers) whose physical and chemical properties include, amongst others, a high degree of chemical inertness, thermal stability and resistance to oxidation.

Silicone fluids (oils) are usually linear chains of polydimethylsiloxane (PDMS) which have a wide range of chain lengths and molecular masses. Cyclic polydimethylsiloxanes also occur and are important intermediates in the manufacture of the linear chain fluids. They are virtually insoluble in water.

Silicone gels have lightly cross-linked polysiloxane networks, swollen with PDMS fluid to produce a cohesive mass. The PDMS fluid is not chemically bound to the crosslinked network but is retained only by physical means, as water is in a sponge, and there is a tendency for the fluid to "bleed". The degree of cross-linking and amount of fluid affects the physical properties of the gel and the rate at which fluid

"bleeds" from it. Once suitably cross-linked, silicone gels retain their form without external containment.

Silicone elastomers are extensively cross-linked and contain little free PDMS fluid. The barrier coating of breast implant shells is a special silicone elastomer which is selected specifically to minimise migration of PDMS from the implants. The tensile strength and tear resistance of silicone elastomers may be increased by addition of amorphous silica which is usually pre-treated with organosilicon compounds to enable it to be tightly incorporated into the polymer network.

2. Measurement of silicone

Silicone materials contain a relatively high proportion of silicon (in general, about 20% by mass for PDMS). Quantitative measurement of silicon has therefore proved to be a convenient means of determining the silicone content of industrial materials. This method has the advantage of greater simplicity, in comparison with methods specific to silicone groups. The analyses must make allowance for the possibility of high levels of adventitious contamination of reagents and equipment arising from the wide natural distribution of silicon in the form of silica and silicates.

While in industrial applications it is convenient to measure silicon as a way to determine the silicone content of materials, it does not follow that the same proportions apply in the human body: in other words, you cannot assume that silicon is an indicator of silicone in the body. Silicon levels by themselves should not be interpreted as an accurate measure of silicone content in body fluids.

3. Uses of silicone

There is widespread use of silicone materials and it is difficult to avoid exposure to them (see Table 1). Silicone is incorporated into medicines; used in food processing (for example, canning and ready meals); used in a wide range of medical devices; used as putty and sealants. The use of silicone oils in food processing and food contact can give rise to systemic exposure to small chain silicone components which are known to be absorbed through the gastrointestinal tract. Silicone is used in domestic and personal products such as cleaning solvents, handcream, hair and skin products, and antiperspirants. It may be absorbed orally or through the skin and absorption can be measured on a scale from 'minimal' to 'well'.

Silicone is also incorporated in some medicines and medical devices. For example, silicone oil is commonly used as a lubricant in syringes and blood giving sets. People with insulin dependent diabetes are exposed to small but regular doses of silicone oil, resulting in a large, cumulative exposure to silicone over a period of time. Silicones are also used during surgery to repair retinal detachment.

Table 1 : Common uses of and exposure to silicone.

Chemical name (designation)	Type	Uses	Amount used	Oral absorption	Dermal absorption	Molecular weight	Water solubility	No. of siloxane	No. of methyl

							(ppm)	units	groups
hexamethyl-disiloxane (L2)	linear	synthesis cleaning solvent handcream and cleanser	various various <10%	moderate or well	low or moderate	163	930	2	6
octamethyl-trisiloxane (L3)	linear	cleaning solvent	various	moderate	low	236	34	3	8
decamethyl-tetrasiloxane (L4)	linear			low or moderate	minimal or low	310	34	4	10
dodecamethyl-pentasiloxane (L5)	linear			low	minimal	384	0.07	5	12
tetradecamethyl-hexasiloxane (L6)	linear			minimal	minimal	458	~0	6	14
hexamethyl-tricyclosiloxane (D3)	cyclic	synthesis	various	well	low or moderate	222	1500	3	6
octamethyl-tetracyclo-siloxane (D4)	cyclic	synthesis hair care products skin care products antiperspirants and deodorants cleaning solvent	various 2-7% 10-20% 20-50% various	well	low or moderate	296	50	4	8
decamethyl-pentacyclo-siloxane (D5)	cyclic	synthesis hair care products skin care products antiperspirants and deodorants cleaning solvent	various 2-7% 10-20% 20-50% various	moderate	low	370	12	5	10
dodecamethyl-hexacyclo-siloxane (D6)	cyclic	synthesis hair care products skin care products antiperspirants and deodorants	various 2-7% 10-20% 20-50%	low	minimal or low	444	~0	6	12
silicone polymers	linear polymer	plasticiser industrial materials industrial additives paint additives synthetic fibres surface treatments textiles detergents cleaning products food packaging food processing cosmetics pharmaceutical glassware medical devices	1-5% 10-100% 1ppm-100% 1ppm-2% 1ppm-5% <1% 1ppm-2% 1ppm-0.1% 1ppm-10% <1-10ppm <10ppm <1-5% 5-10% 1% 100%	negligible	negligible	>7000	~0	>100	200

Note: All small chain silicones with and without other identified uses are found as trace components in

polymers at ppm levels, actual values vary between each use of silicone polymer. The typical levels for these low molecular weight silicones in breast implant gel are 800-1500 ppm.

Description of absorption terms:

Amount	Description
<0.1%	negligible
<1%	minimal
<5%	low
5-40%	moderate
>40%	well

Categories are based on actual studies where performed or are estimated based on physicochemical properties and data on related compounds.

If you have any comments you wish to make about this publication please send an email to the following address, mail@silicone-review.gov.uk

This site is best viewed using Netscape 3 or IE3 and above

Livermore Scientists Join DOE Consortium In Partnering With Private Company To Develop Artificial Retina

CHICAGO, Ill. - A Department of Energy consortium of national laboratories including Livermore and universities today signed an agreement with Second Sight Medical Products Inc. to jointly develop technology that could restore sight to those who have lost vision later in life.

The Cooperative Research and Development Agreement (CRADA) allows Second Sight Medical Products Inc. of Sylmar, Calif. to obtain a limited exclusive license for inventions developed during the DOE Retinal Prosthesis Project.

"The Department of Energy has led the way to many scientific breakthroughs, especially when several scientific disciplines combined to make a whole greater than the sum of the parts," Energy Secretary Spencer Abraham said. "This project is one such example where biology, physics and engineering have joined forces to deliver a capability that will enable blind people to see. This agreement between the DOE laboratories and the private sector will facilitate transfer of many aspects of DOE technology to a clinical device that has the potential of restoring sight to millions of blind individuals.

An artificial retina could restore vision to millions of people suffering from eye diseases such as macular degeneration (the leading cause of blindness in people over 60), retinitis pigmentosa (the leading cause of blindness in people under 50), or those who are legally blind due to the loss of photoreceptor function.

Lawrence Livermore partnered with four other national laboratories, three universities and Second Sight on the project.

Engineers from LLNL's Center for Micro- and Nanotechnology specifically are developing a flexible silicone implant (microelectrode array) that sits on the surface of the retina. The electrode array can contact delicate retinal tissue without damaging it.

The implantable retinal prosthesis is based on a system that converts a video camera signal into a stimulation pattern that is applied directly to the intra-ocular retinal surface. This is referred to as an epiretinal implant - the device is in contact with the surface of the retina. Visual signals are captured by a small video camera in the eyeglasses of the blind person and processed through a microcomputer worn on a belt.

Although the device will not restore full vision, it is expected to provide enough optical resolution for patients to read and recognize fine shapes.

LLNL's pioneering use of polydimethlsiloxane, or PDMS, allowed the microelectrode array to conform to the curved shape of the retina.

"PDMS has the look and feel of thin plastic food wrap," said Livermore's principal investigator, Courtney Davidson. "Yet it's biocompatible, making it a good candidate material for long-term implants."

Partners in the project include Oak Ridge, Argonne, Sandia and Los Alamos national laboratories, the University of California, Santa Cruz, the University of Southern California Doheny Eye Institute and North Carolina State University.

Project leader Dr. Mark Humayun of USC has shown that electrical stimulation of the viable retinal cells can result in visual perception. These findings helped spark the worldwide effort to develop a retinal prosthesis device.

The first patient to receive a prototype implant in 2002 was able to see large letters and to differentiate between a cup, a plate and a knife after being blind for more than 50 years. To date, six volunteers have received implants of a micro-electronic device that rests on the surface of the retina to perform the function of normal photoreceptive cells.

The artificial retina technology was featured today at the department's "What's Next Expo," an event designed to showcase the newest, most innovative, cutting-edge scientific and technological advances to interest young people in pursuing careers in math and science.

Second Sight was founded in 1998 to create a retinal prosthesis to provide sight to patients blinded from outer retinal degenerations.

Founded in 1952, Lawrence Livermore National Laboratory is a national security laboratory, with a mission to ensure national security and apply science and technology to the important issues of our time. Lawrence Livermore National Laboratory is managed by the University of California for the U.S. Department of Energy's National Nuclear Security Administration.